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*Admitted only in Maryland
*Admitted only in Virginia
*Practice Limited to
Federal Agencies

March 15, 2004

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Art Unit To Be Assigned

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Re: U.S. Utility Patent Application
Application No. 10/734,625; Filed: December 15, 2003
For: **Lipoxygenase Inhibitors as Hypolipidemic and Anti-Hypertensive Agents**
Inventors: **ALLAN et al.**
Our Ref: **1633.0400002/SRL/NJL**

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. PTO-1449 citing 67 documents; and
3. Copies of 40 cited documents; and
4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
March 15, 2004
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Nancy J. Leith

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Agent for Applicants
Registration No. 45,309

SRL/NJL:cpn
Enclosures

241331-1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Allan *et al.*

Appl. No.: 10/734,625

Filed: December 15, 2003

For: **Lipoxygenase Inhibitors as
Hypolipdemic and Anti-
Hypertensive Agents**

Confirmation No.: *To Be Assigned*

Art Unit: *To Be Assigned*

Examiner: *To Be Assigned*

Atty. Docket: 1633.0400002/SRL/NJL

Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents AR1-AT13 and AL1 are also provided.

Copies of documents AA1 to AD3 are not provided in accordance with the U.S. Patent and Trademark Office pre-OG notice of July 11, 2003, which states "[t]he Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003."

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may

not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

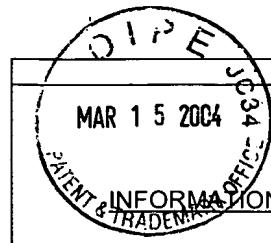
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Date: March 15, 2004

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FORM PTO-1449 PATENT & TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1633.0400002/SRL/NJL	APPLICATION NO. 10/734,625
	FIRST NAMED INVENTOR Allan et al.	
	FILING DATE December 15, 2003	ART UNIT To Be Assigned

U.S. PATENT DOCUMENTS

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	AA						
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FOREIGN PATENT DOCUMENTS

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	AL						Yes No
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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	4	Gowri, M.S., et al., "Masoprolol Lowers Blood Pressure in Rats With Fructose-Induced Hypertension," <i>Am. J. Hypertension</i> , 12:744-746, Elsevier Science (1999)
AS	4	Gowri, M.S., et al., "Masoprolol decreases rat lipolytic activity by decreasing the phosphorylation of HSL," <i>Am. J. Physiol. Endocrinol. Metab.</i> 279:E593-E600, American Physiological Society (2000)
AT	4	Guha, M., et al., "Molecular Mechanisms of Tumor Necrosis Factor α Gene Expression in Monocytic Cells via Hyperglycemia-induced Oxidant Stress-dependent and -independent Pathways," <i>J. Biol. Chem.</i> 275:17728-17739, The American Society for Biochemistry and Molecular Biology, Inc. (2000)

EXAMINER	DATE CONSIDERED
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'	AA3	5,342,952	08/30/1994	Butler et al.			10/12/1993
.	AB3	5,354,772	10/11/1994	Kathwala			11/24/1993
.	AC3	5,356,896	10/18/1994	Kabadi et al.			12/22/1992
.	AD3	5,489,691	02/06/1996	Butler et al.			05/15/1995
.	AE	6,191,169 B1	02/20/2001	Nadler et al.			11/03/1997
.	AF						
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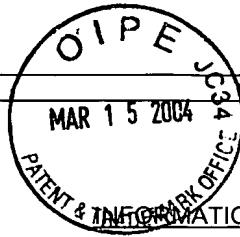
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

		<u>3</u>	Das, U.N., "Is Metabolic Syndrome X an Inflammatory Condition," <i>Exp. Biol. Med.</i> 227:989-997, Society for Experimental Biology and Medicine (December 2002)
		<u>3</u>	Feingold, K.R., et al., "Beneficial effects of cytokine induced hyperlipidemia," <i>Z. Ernährungswiss</i> 37:66-74, Steinkopff Verlag (1998)
		<u>3</u>	Gillard, J., et al., "L-663,536 (MK-886) (3-[1-(4-chlorobenzyl)-3-t-butyl-thio-5-isopropylindol-2-yl]-2,2-dimethylpropanoic acid), a novel, orally active leukotriene biosynthesis inhibitor," <i>Can. J. Physiol. Pharmacol.</i> 67: 456-464, National Research Council of Canada (1989)

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EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA1	4,231,938	11/04/1980	Monaghan et al.			06/15/1979
AB1	4,294,926	10/13/1981	Monaghan et al.			01/23/1980
AC1	4,319,039	03/09/1982	Albers-Schonberg			08/11/1980
AD1	4,346,227	08/24/1982	Terahara et al.			06/05/1981
AE1	4,393,075	07/12/1983	Terao et al.			03/26/1981
AF1	4,410,629	10/18/1983	Terahara et al.			02/24/1982
AG1	4,444,784	04/24/1984	Hoffman et al.			12/18/1980
AH1	4,537,859	08/27/1985	Terahara et al.			11/18/1982
AI1	4,681,893	07/21/1987	Roth			05/30/1986
AJ1	4,738,986	04/19/1988	Kneen et al.			03/10/1987
AK1	4,820,850	04/11/1989	Verhoeven et al.			07/10/1987

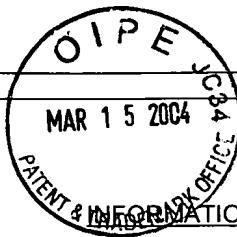
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EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
AL1	WO 84/02131					Yes No
AM						Yes No
AN						Yes No
AO						Yes No
AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	1	Ashida, Y., et al., "Pharmacological Profile of AA-861, A 5-Lipoxygenase Inhibitor," <i>Prostaglandins</i> 26:955-972, Elsevier Science (1983)
AS	1	Azhar, S., et al., "Alteration of the Adrenal Antioxidant Defense System During Aging in Rats," <i>J. Clin. Invest.</i> 96:1414-1424, American Society for Clinical Investigation (1995)
AT	1	Babu, P.S., and Srinivasan, K., "Hypolipidemic action of curcumin, the active principle of turmeric (<i>Curcuma longa</i>) in streptozotocin induced diabetic rats," <i>Mol. Cell. Biochem.</i> 166:169-175, Kluwer Academic Publishers (1997)

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	4,911,165	03/27/1990	Lennard et al.			12/12/1988
.	AB2	4,916,239	04/10/1990	Treiber			07/19/1988
	AC2	4,929,437	05/29/1990	Tobert			02/02/1989
	AD2	5,030,447	07/09/1991	Joshi et al.			03/31/1988
	AE2	5,081,138	01/14/1992	Gillard et al.			12/09/1987
	AF2	5,118,853	06/02/1992	Lee et al.			02/26/1991
	AG2	5,177,080	01/05/1993	Angerbauer et al.			11/26/1991
	AH2	5,180,589	01/19/1993	Joshi et al.			05/20/1991
	AI2	5,189,164	02/23/1993	Kapa et al.			02/20/1990
	AJ2	5,273,995	12/28/1993	Roth			02/26/1991
	AK2	5,290,946	03/01/1994	Lee et al.			11/23/1992

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	AL						Yes No
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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	2	Bantle, J.P., et al., "Effects of dietary fructose on plasma lipids in healthy subjects," <i>Am. J. Clin. Nutr.</i> 72:1128-1134, American Society for Clinical Investigation (2000)
AS	2	Bhattacherjee, P., et al., "The Effects of a Novel Series of Selective Inhibitors of Arachidonate 5-Lipoxygenase on Anaphylactic and Inflammatory Responses," <i>Ann. New York Acad. Sci.</i> , 307-320, The New York Academy of Sciences (1988)
AT	2	Brindley, D.N., et al., "The Involvement of Glucocorticoids in Regulating the Activity of Phosphatidate Phosphohydrolase and the Synthesis of Triacylglycerols in the Liver," <i>Biochem. J.</i> 180: 195-199, The Biochemical Society (1979)

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FORM PTO-1449

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1633.0400002/SRL/NJLAPPLICATION NO.
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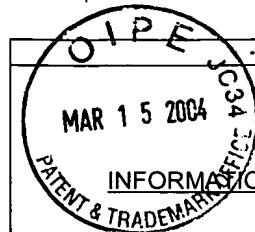
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	5	Hallfrisch, J., "Metabolic effects of dietary fructose," <i>FASEB J.</i> 4:2652-2660, Federation of American Societies for Experimental Biology (1990)
AS	5	Hammes, H.-P., et al., "Benfotiamine blocks three major pathways of hyperglycemic damage and prevents experimental diabetic retinopathy," <i>Nat. Med.</i> 9:294-299, Nature Publishing Company (March 2003)
AT	5	Han, T.S., et al., "Prospective Study of C-Reactive Protein in Relation to the Development of Diabetes and Metabolic Syndrome in the Mexico City Diabetes Study," <i>Diabetes Care</i> 25:2016-2021, American Diabetes Association (November 2002)

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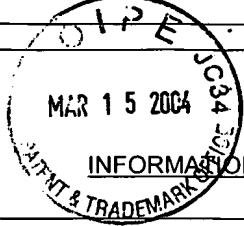
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	6	Hiromi, J., et al., "A central role for JNK in obesity and insulin resistance," <i>Nature</i> 420:333-336, Nature Publishing Company (November 2002)
AS	6	Inoue, I., et al., "Effect of Troglitazone (CS-045) and Bezafibrate on Glucose Tolerance, Liver Glycogen Synthase Activity, and β -Oxidation in Fructose-Fed Rats," <i>Metabolism</i> 44:1626-1630, W.B. Saunders Company (1995)
AT	6	Jonkers, I.J., et al., "Severe Hypertriglyceridemia with Insulin Resistance Is Associated with Systemic Inflammation: Reversal with Bezafibrate Therapy in a Randomized Controlled Trial," <i>Am. J. Med.</i> 112: 275-280, Excerpta Medica, Inc. (March 2002)

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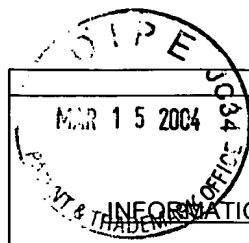
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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	7	Knox, A.M., et al., "Control of Hepatic Triacylglycerol Synthesis. Diurnal Variations in Hepatic Phosphatidate Phosphohydrolase Activity and in the Concentrations of Circulating Insulin and Corticosterone in Rats," <i>Biochem. J.</i> 180: 441-443, The Biochemical Society (1979)
	AS	7	Kraemer, F.B., et al., "Adrenal Neutral Cholesteryl Ester Hydrolase: Identification, Subcellular Distribution, and Sex Differences," <i>Endocrinol.</i> 143:801-806, The Endocrine Society (March 2002)
	AT	7	Mangaloglu, L., et al., "Treatment With Atorvastatin Ameliorates Hepatic Very-Low-Density Lipoprotein Overproduction in an Animal Model of Insulin Resistance, the Fructose-Fed Syrian Golden Hamster: Evidence That reduced Hypertriglyceridemia Is Accompanied by Improved Hepatic Insulin Sensitivity," <i>Metabolism</i> 51: 409-418, W.B. Saunders (April 2002)

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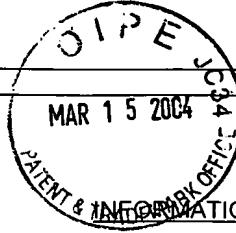
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	8	McIntosh, M., et al., "Opposing Actions of Dehydroepiandrosterone and Corticosterone in Rats," <i>Proc. Soc. Exp. Med.</i> 221:198-206, Society for Experimental Biology and Medicine (1999)
AS	8	Medicherla, R., et al., "Impaired activation of AP-1 and altered expression of constituent proteins in rat adrenal during ageing," <i>Mech. Aging Dev.</i> 122:1169-1186, Elsevier Science Ireland Ltd. (June 2001)
AT	8	Memon, R.A., et al., "Tumor Necrosis Factor Mediates the Effects of Endotoxin on Cholesterol and Triglyceride Metabolism in Mice," <i>Endocrinol.</i> 132:2246-2253, The Endocrine Society (1993)

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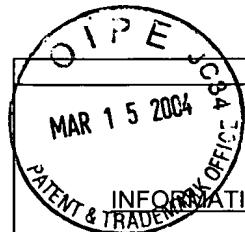
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AR	9	Nagai, Y., et al., "Amelioration of high fructose-induced metabolic derangements by activation of PPAR α ," <i>Am. J. Physiol. Endocrinol. Metab.</i> 282:E1180-E1190, American Physiological Society (January 2002)
AS	9	Okamoto, T., et al., "Angiogenesis induced by advanced glycation end products and its prevention by cerivastatin," <i>FASEB J.</i> 16:1928-1930, Federation of American Societies for Experimental Biology (December 2002)
AT	9	Park, O.-J., et al., "Mechanisms of fructose-induced hypertriglyceridaemia in the rat," <i>Biochem. J.</i> 282:753-757, The Biochemical Society (1992)

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1633.0400002/SRL/NJLAPPLICATION NO.
10/734,625FIRST NAMED INVENTOR
Allan et al.FILING DATE
December 15, 2003ART UNIT
To Be Assigned

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

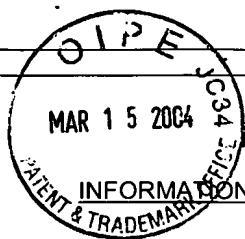
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>10</u>	Radmark, O., et al., "The Inhibitory Effects of BW 755C on Arachidonic Acid Metabolism in Human Polymorphonuclear Leukocytes," <i>FEBS Lett.</i> 110: 213-215, Elsevier/North Holland (1980)
AS	<u>10</u>	Rouzer, C.A., et al., "MK886, a Potent and Specific Leukotriene Biosynthesis Inhibitor Blocks and Reverses the Membrane Association of 5-Lipoxygenase in Ionophore-challenged Leukocytes," <i>J. Biol. Chem.</i> 265:1436-1442, The American Society for Biochemistry and Molecular Biology, Inc. (1990)
AT	<u>10</u>	Scribner, K.A., et al., "Masoprolol Decreases Serum Triglyceride Concentrations in Rats With Fructose-Induced Hypertriglyceridemia," <i>Metabolism</i> 49:1106-1110, W.B. Saunders Company (2000)

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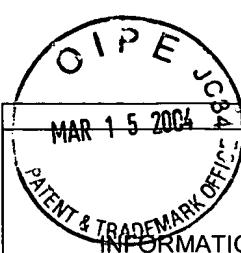
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AR	11	Tagari, P., et al., "Assessment of the <i>in vivo</i> biochemical efficacy of orally active leukotriene biosynthesis inhibitors," <i>Agents Action</i> 40:62-71, Birkhäuser Verlag (1993)
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AT	11	Uchida, K., et al., "Activation of Stress Signaling Pathways by the End Product of Lipid Peroxidation," <i>J. Biol. Chem.</i> 274: 2234-2242, The American Society for Biochemistry and Molecular Biology, Inc. (1999)

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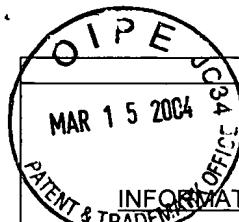
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AR	12	Uysal, K.T., et al., "Protection from obesity-induced insulin resistance in mice lacking TNF- α function," <i>Nature</i> 389:610-614, Nature Publishing Company (1997)
AS	12	Ventre, J., et al., "Targeted Disruption of the Tumor Necrosis Factor- α Gene," <i>Diabetes</i> 46:1526-1531, American Diabetes Association (1997)
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AR	13	Yoshimoto, T., et al., "2,3,5-Trimethyl-6-(12-hydroxy-5,10-dodecadiynyl)-1,4-benzoquinone (AA861), a Selective Inhibitor of the 5-Lipoxygenase Reaction and the Biosynthesis of Slow-Reacting Substance of Anaphylaxis," <i>Biochim. Biophys. Acta</i> 713:470-473, Elsevier Biomedical Press (1982)
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